DIABETES COLLABORATIVE REGISTRY®

Using the Diabetes Collaborative Registry (DCR) to Estimate the Potential Real-World Impact of the IRIS Trial on Improving Outcomes in Patients with Cerebrovascular Disease

Suzanne V. Arnold, Silvio E. Inzucchi, Fengming Tang, Darren K. McGuire, Sanjeev N. Mehta, Abhinav Goyal, Thomas M. Maddox, Laurence S. Sperling, Daniel Einhorn, Nathan D. Wong, Mikhail Kosiborod

Saint Luke's Mid America Heart Institute/UMKC, Kansas City MO; Yale University, New Haven CT; University of Texas Southwestern, Dallas TX; Joslin Diabetes Center, Boston MA; Emory University, Atlanta GA; VA Eastern Colorado Health Care System, Denver CO; University of California, San Diego CA; University of California, Irvine CA

BACKGROUND

- Thiazolidinedione use has markedly decreased since concerns arose regarding the CV safety of rosiglitazone
- The IRIS trial demonstrated pioglitazone reduced the risk of MI and stroke in patients with recent stroke or TIA and insulin resistance (but without overt diabetes)
- We estimated the current use and potential impact of pioglitazone in patients enrolled in the Diabetes Collaborative Registry® (DCR)
- DCR is a US-based outpatient registry of patients with diabetes or prediabetes seen in cardiology, endocrinology, and primary care practices and currently encompasses 374 practices and 5114 providers

METHODS

- **Study Population:** 58,466 patients with pre-diabetes or diet-controlled diabetes (HbA1c <7% and on no medications for diabetes [except pioglitazone])
- We assessed the percentage of these patients who would have met the main eligibility requirements for the IRIS trial
- Age ≥40 years and prior stroke or TIA
- No history of heart failure or moderate/severe LV dysfunction
- We then estimated the number of events potentially avoided among the eligible patients using the published absolute risk reductions (both overall and per 100-patient years).
- The most recent visit for each patient was used for analysis

Figure: Eligibility for IRIS in DCR and Use of Pioglitazone

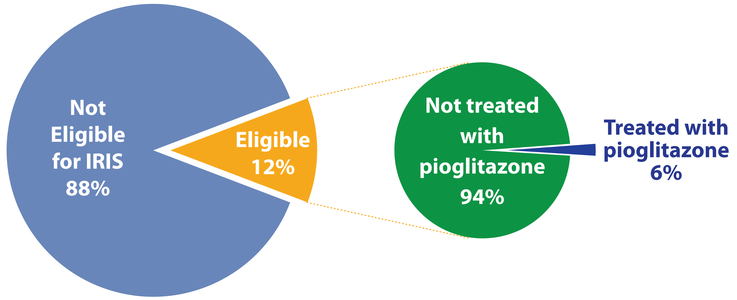

Table 1: Patient Factors

	Pioglitazone (n=146)	No Pioglitazone (n=6,626)	p-value
Age	72.6 y	70.4 y	0.019
Male sex	55%	52%	0.54
White race	90%	90%	0.88
BMI	32.0 kg/m^2	30.1 kg/m^2	0.001
HbA1c	6.1%	5.9%	<0.001
Hypertension	93%	88%	0.057
Systolic BP	132 mmHg	130 mmHg	0.098
Diastolic BP	73 mmHg	75 mmHg	0.064
Dyslipidemia	90%	92%	0.64
CAD	69%	56%	0.001
Prior MI	12%	15%	0.43
Prior CABG	16%	12%	0.083
PAD	22%	23%	0.85
Prior stroke	69%	74%	0.15
Prior TIA	41%	38%	0.43
Atrial fibrillation	24%	21%	0.30
CKD	14%	12%	0.42
Current smoker	10%	14%	0.44

Table 2: Possible Events Avoided

	Event Rate (Total)		Event Rate (Annualized)		Potential Events Avoided	
	Drug	Placebo	Drug	Placebo	Total (4.8 y)	Per Year
All cause death	7.0%	7.5%	1.46%	1.57%	33	7
CV death	6.3%	7.7%	1.32%	1.61%	93	19
Myocardial infarct	2.7%	4.0%	0.56%	0.84%	86	19

CONCLUSIONS

- In a large US-based outpatient registry, we found that 12% of outpatients with prediabetes or diet-controlled diabetes met the main eligibility criteria for IRIS
- The limited number of eligible patients reflects the narrow inclusion criteria of the trial and also the lack of screening for prediabetes and insulin resistance
- Pioglitazone is rarely used but could have a substantial impact on eligible patients
- Future studies should examine the CV benefits of pioglitazone in the broader population of patients with cerebrovascular disease and overt diabetes or in patients with insulin resistance and other CV disease

DISCLOSURES

- **This research was supported by the American College of Cardiology Foundation. Additional organizations partner with ACCF on the Diabetes Collaborative Registry. The views expressed in this abstract represent those of the author(s), and do not necessarily represent the official views of the ACCF or its partnering organizations**
- **For more information go to www.thediabetesregistry.org**
- **The registry is sponsored by AstraZeneca (Founding Sponsor) and Boehringer Ingelheim Pharmaceuticals, Inc**